STATE OF WASHINGTON
HEALTH CARE AUTHORITY
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December 17, 2014

URGENT

TO: Prescribers

FROM: Apple Health (Washington State Medicaid)

SUBJECT: Hepatitis C treatment paid under FFS benefit

Hepatitis C Prior Authorization and Treatment Policy

Effective for dates on and after January 1, 2015, immune modulators and anti-viral medications to treat chronic Hepatitis C virus (HCV) infection will be excluded from the Apple Health Managed Care Organizations' (MCO) benefit and will be covered through the Apple Health Fee-For-Service (FFS) program.

All coverage for immune modulators and anti-viral medications to treat HCV will be covered through the FFS program for Apple Health clients, according to the attached Hepatitis C Prior Authorization and treatment policy.

Other medical and pharmaceutical services related to the diagnosis and treatment of HCV are still covered by the client's MCO.

Prescribers my initiate the authorization process by submitting a prescription to the dispensing pharmacy, who will initiate the authorization process with HCA. Prescribers will then receive a faxed request for information that must be returned to the agency including relevant chart notes and labs.

Specifically for HCV medications, prescribing providers may also request authorization by contacting the agency at 1-800-562-3022 ext. 15483 and stating they are requesting authorization for an HCV medication.

If you have already requested authorization for HCV medications through the client's MCO but have not yet received approval, prescribers are encouraged to initiate the authorization process with the FFS program as soon as possible on or after January 2nd.

- Please see next page for HCA Hepatitis C Coverage Criteria -

Washington Health Care Authority (HCA): Hepatitis C Treatment Policy
(Effective January 1, 2015)

The intent of this policy is to define clinical characteristics that all plans must use to identify patients who qualify for HCV treatment. It is the expectation that plans and providers will work together to remove barriers to ensure patients get the care they need according to this treatment policy in a timely manner. HCA Plans must cover hepatitis C treatment when the following criteria have been met:

INCLUSION CRITERIA

1. Baseline detectable HCV RNA viral load;
   AND

2. HCV Infection with at least one of the conditions listed in 2a through 2c:
   a. Metavir Fibrosis Score of ≥ F3 as measured by one of the following:
      i. APRI (AST to platelet ratio index) ≥ 1.5 AND FibroSURE ≥ 0.49[1]
      ii. FibroScan ≥ 7.1 AND FibroSURE ≥ 0.49[1]
      iii. FibroScan ≥ 7.1 AND APRI ≥ 1.5[1]
      iv. Biopsy ≥ F3
      v. Abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially the left lobe; tortuous hepatic arteries; ascites; or portal hypertension);

   OR

   b. HIV or HBV coinfection[2] with a Metavir Fibrosis Score ≥ F2 as measured by one of the following:
      i. FibroScan ≥ 7.1
      ii. APRI ≥ 1.5
      iii. APRI = 0.5 – 1.5 AND FibroSURE ≥ 0.49
      iv. Biopsy ≥ F2

   OR

   c. Metavir Score = F0 – F4 with one of the following:
      i. Post solid organ transplant (e.g. Heart, Kidney, Liver) [2-4]
      ii. Awaiting Liver transplant[2-4]
      iii. Stage I-III Hepatocellular Carcinoma meeting Milan Criteria[5]
      iv. HCV Infection post liver transplant
      v. Severe complications of HCV as defined below
         A. Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations[2]
         B. HCV induced renal disease (e.g. Nephrotic syndrome or membranoproliferative glomerulonephritis (MPGN)) [2]
      vi. Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7 – 12 (CPT Class B/C)[6] and MELD is ≤ 20[6];

AND

3. Patients satisfying inclusion criterion 1 and 2 with history of Alcohol Use Disorder must be abstinent from alcohol use for 6 months or longer[2]. Exceptions will be considered for patients who have abstained from alcohol for at least 3 months if they are:
    a. Receiving treatment through a DBHR approved facility; or
    b. under the care of an Addiction Medicine specialist; and
    c. Abstain from alcohol use during treatment
    d. ***Documentation supporting these exceptions will be required***;

AND

4. Patients satisfying inclusion criterion 1 and 2 with a history of IV drug use must be abstinent from IV drugs for at least 3 months[8-11]. Patients with IV drug use within the last 3 months will be considered for treatment if they are:
    a. Receiving opiate substitution therapy through a DBHR approved facility; or
    b. Receiving medication assisted treatment (MAT) from an Addiction Medicine specialist or a buprenorphine waived provider[10,11]
    Documentation supporting these exceptions will be required;

EXCLUSION CRITERIA: Patients with the following conditions are not eligible for HCV treatment

1. Creatinine Clearance (CrCL) < 30 mL/min or on hemodialysis
2. Pregnant or planning on becoming pregnant
3. Severe end organ disease and not eligible for transplant (e.g. liver, heart, lung, kidney)
4. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment
5. Patients who in the professional judgment of the primary treating clinician would not achieve a long term clinical benefit from HCV treatment (e.g. patients: with multisystem organ failure; receiving palliative care; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)
6. Decompensated liver disease with CPT > 12 or MELD > 20[6]
7. MELD < 20[6] and one of the following:
    a. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
    b. Malignancy outside the liver not meeting oncologic criteria for cure
    c. Hepatocellular carcinoma with metastatic spread
    d. Intrahepatic cholangiocarcinoma
    e. Hemangiosarcoma
    f. Uncontrolled sepsis

OTHER REQUIREMENTS FOR APPROVAL:

1. Prescriber is a gastroenterologist, hepatologist or infectious disease specialist, or prescriber is participating in and consults with Project ECHO or one of the listed specialists (requires consultation note or documentation of phone call). Exceptions may be made for other non-specialist providers who work in coordination with an organized

system of care, have received training in hepatitis C diagnosis, staging and treatment protocols, and have ready access to specialists that treat HCV[2];
AND

2. Patient has attended a medical care visit with the treating clinician to discuss the pros and cons of antiviral therapy, the importance of adherence to treatment, and the risk factors for fibrosis progression.
AND

3. Patient must agree to participate in case-management or adherence monitoring program if required by the plan;
AND

4. Both the treating clinician and the patient must be confident that the patient can effectively start and successfully adhere to treatment. The treating clinician must attest that the patient has been evaluated for "psychosocial readiness" for treatment, including identification of potential impediments to effective treatment (e.g. difficulties with compliance, missing appointments, adequate social support, adequate control of mental health conditions). Potential impediments to successful treatment must be addressed prior to initiating treatment;
AND

5. Providers must agree to submit an HCV RNA viral load after completion of full course of antiviral treatment upon the request of the plan to track treatment success.

QUANTITY AND DISPENSING LIMITS

Patients meeting the criteria above may receive HCV treatment. Approved antiviral regimens in Table 1 may be limited to 7 days or 14 days supply per dispensing with exceptions for members with limited transportation to retail pharmacies. Plans may limit dispensing to a single specialty pharmacy with exceptions for members without stable mailing addresses.

Table 1: HCA Approved Hepatitis C Treatment Regimens
(This table will be updated as new drugs and new evidence becomes available)

Genotype 1		**Treatment regimen**	**SVR rate**
Naïve	Without Cirrhosis & HCV RNA VL < 6 million in last 3 months	LDV/SOF x 8 wks	97%[12]
	Without Cirrhosis & HCV RNA VL ≥ 6 million in last 3 months	LDV/SOF x 12 wks	95%[7] - 99%[13]
	With cirrhosis	LDV/SOF x 12 wks	97%[13]
Experienced [A]	Without cirrhosis	LDV/SOF x 12 wks	95% [14]
	With cirrhosis	LDV/SOF x 24 wks LDV/SOF + RBV x 12 wks[B]	98%[13] - 100%[14] 96%[15]
Genotype 2		**Treatment regimen**	**SVR rate**
Naïve and Experienced [A]		SOF + RBV x 12 wks	TN: 93%[16] - 97%[17, 18] TE: 88%[16] - 90%[18]
Genotype 3		**Treatment regimen**	**SVR rate**
Naïve or Experienced [A]	PEG-eligible	SOF + PEG + RBV x 12 wks	Naïve 97%[19] Exp. 83%[20]
	PEG- ineligible[C]	SOF + RBV x 24 wks	Naïve 94%[21] Exp. 79%[19]
		LDV/SOF + RBV x 12 wks[B]	Naïve 100% [22]
Genotype 4, 5, 6		**Treatment regimen**	**SVR rate**
Naïve and Experienced [A]	PEG-eligible	SOF + PEG + RBV x 12 wks	96%[17]
	PEG-ineligible[C]	SOF + RIB x 24 wks[B]	93% [21]
Genotype 1-4		**Treatment regimen**	**SVR rate**
HCC awaiting Transplant		SOF + RIB X 48 wks or transplant	70%[5]
GT 1 & 4 Post Liver Transplant		SOF + RIB x 24 wks LDV/SOF + RIB x 12 wks [B]	70%[23] 96%[24]
GT 1 & 4 CTP Class B/C Liver decompensation (MELD ≤20)		LDV/SOF + RBV x 12 wks[B] LDV/SOF x 24 wks[B]	86-87%[6] Studies on Going

Key: PEG = pegylated interferon; RBV = ribavirin; LDV/SOF = ledipasvir/sofosbuvir
A = Failure with PEG+RBV or PEG+RBV+PI; or for GT1 failure of prior SOF+PEG+RIB
B = Not FDA approved
C = Interferon ineligible or intolerant criteria: Platelet count <75,000, Severe mental health conditions that may be exacerbated by interferon; Autoimmune hepatitis; Autoimmune diseases that may be exacerbated by interferon-mediated immune modulation; Inability to complete a prior treatment course due to documented interferon-related adverse effects; Hemoglobinopathies (thalassemia major and sickle cell) in combination with Ribavirin; Child Pugh > 6 (Class B and C) in cirrhotic patients; Child Pugh ≥ 6 (Class B and C) in cirrhotic patients with HIV coinfection

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